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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,125	03/28/2001	Etsuya Matsutani	2556USOP	7053

23115 7590 10/03/2003

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	17

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,125	MATSUTANI ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- Th MAILING DATE of this communication appears on the cov r sheet with th correspond nce address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *election facsimile cover sheet* .

DETAILED ACTION

1. The amendment filed September 23, 2002 in Paper No. 5 is acknowledged and has been entered. Claims 4 and 5 have been amended.

2. The amendment filed May 29, 2003 in Paper No. 15 is acknowledged and has been entered.

3. Claims 1-11 are pending in the application and are currently subject to the following restriction.

Election/Restrictions

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, insofar as the claims are drawn to a composition containing a hormonal agent, wherein said hormonal agent is a LH-RH derivative, wherein said LH-RH derivative is an LH-RH agonist, wherein said LH-RH agonist is a peptide represented by SEQ ID NO: 1, and optionally containing in addition to said hormonal agent, an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is EGF or a substance possessing substantially the same activity as EGF, the use of said hormonal agent to retard transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, the use of said hormonal agent to produce a pharmaceutical for use in retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, and a method for retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer comprising administering said hormonal agent to a mammal.

Group II, claim(s) 1-11, insofar as the claims are drawn to a composition containing a hormonal agent, wherein said hormonal agent is a LH-RH derivative, wherein said LH-RH derivative is an LH-RH agonist, wherein said LH-RH agonist is a peptide represented by SEQ ID NO: 1, and optionally containing in addition to said hormonal agent, an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is insulin or a substance possessing substantially the same activity as insulin, the use of said hormonal agent to retard transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, the use of said hormonal agent to produce a pharmaceutical for use in retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, and a method for retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer comprising administering said hormonal agent to a mammal.

Group III, claim(s) 1-11, insofar as the claims are drawn to a composition containing a hormonal agent, wherein said hormonal agent is a LH-RH derivative, wherein said LH-RH derivative is an LH-RH agonist, wherein said LH-RH agonist is a peptide represented by SEQ ID NO: 1, and optionally containing in addition to said hormonal agent, an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is FGF or a substance possessing substantially the same activity as FGF, the use of said hormonal agent to retard transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, the use of said hormonal agent to produce a pharmaceutical for use in retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, and a method for retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer comprising administering said hormonal agent to a mammal.

Group IV, claim(s) 1-11, insofar as the claims are drawn to a composition containing a hormonal agent, wherein said hormonal agent is a LH-RH derivative,

wherein said LH-RH derivative is an LH-RH agonist, wherein said LH-RH agonist is a peptide represented by SEQ ID NO: 2, and optionally containing in addition to said hormonal agent, an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is EGF or a substance possessing substantially the same activity as EGF, the use of said hormonal agent to retard transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, the use of said hormonal agent to produce a pharmaceutical for use in retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, and a method for retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer comprising administering said hormonal agent to a mammal.

Group V, claim(s) 1-11, insofar as the claims are drawn to a composition containing a hormonal agent, wherein said hormonal agent is a LH-RH derivative, wherein said LH-RH derivative is an LH-RH agonist, wherein said LH-RH agonist is a peptide represented by SEQ ID NO: 2, and optionally containing in addition to said hormonal agent, an agent that inhibits the action of a cell growth factor or receptor thereof, wherein said cell growth factor is insulin or a substance possessing substantially the same activity as insulin, the use of said hormonal agent to retard transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, the use of said hormonal agent to produce a pharmaceutical for use in retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, and a method for retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer comprising administering said hormonal agent to a mammal.

Group VI, claim(s) 1-11, insofar as the claims are drawn to a composition containing a hormonal agent, wherein said hormonal agent is a LH-RH derivative, wherein said LH-RH derivative is an LH-RH agonist, wherein said LH-RH agonist is a peptide represented by SEQ ID NO: 2, and optionally containing in addition to said hormonal agent, an agent that inhibits the action of a cell growth factor or receptor

thereof, wherein said cell growth factor is FGF or a substance possessing substantially the same activity as FGF, the use of said hormonal agent to retard transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, the use of said hormonal agent to produce a pharmaceutical for use in retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer, and a method for retarding transformation of a hormone-dependent cancer to a non-hormone-dependent cancer comprising administering said hormonal agent to a mammal.

5. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of group I is a composition comprising a LH-RH agonist that is a peptide represented by SEQ ID NO: 1 and containing in addition to said hormonal agent, an agent that inhibits the action of EGF or a substance possessing substantially the same activity as EGF, or a receptor thereof.

The special technical feature of group II is a composition comprising a LH-RH agonist that is a peptide represented by SEQ ID NO: 1 and containing in addition to said hormonal agent, an agent that inhibits the action of insulin or a substance possessing substantially the same activity as insulin, or a receptor thereof.

The special technical feature of group III is a composition comprising a LH-RH agonist that is a peptide represented by SEQ ID NO: 1 and containing in addition to said hormonal agent, an agent that inhibits the action of FGF or a substance possessing substantially the same activity as FGF, or a receptor thereof.

The special technical feature of group IV is a composition comprising a LH-RH agonist that is a peptide represented by SEQ ID NO: 2 and optionally containing in addition to

said hormonal agent, an agent that inhibits the action of EGF or a substance possessing substantially the same activity as EGF, or a receptor thereof.

The special technical feature of group V is a composition comprising a LH-RH agonist that is a peptide represented by SEQ ID NO: 1 and optionally containing in addition to said hormonal agent, an agent that inhibits the action of insulin or a substance possessing substantially the same activity as insulin, or a receptor thereof.

The special technical feature of group VI is a composition comprising a LH-RH agonist that is a peptide represented by SEQ ID NO: 1 and optionally containing in addition to said hormonal agent, an agent that inhibits the action of FGF or a substance possessing substantially the same activity as FGF, or a receptor thereof.

Accordingly, groups I-VI do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Claims 1, 2, and 3 are linking claims, linking the inventions of claims 1, 2, and 3, wherein said hormonal agent is an LH-RH derivative, which is an LH-RH agonist selected from the group of agonists consisting of (a) a peptide represented by SEQ ID NO: 1 and (b) a peptide represented by SEQ ID NO: 2.

Claim 6 is a linking claim, linking the inventions of claim 6, wherein said agent is an agent that inhibits the action of a cell growth factor, or a receptor thereof, selected from the group consisting of (a) EGF or a substance possessing substantially the same activity as EGF, (b) insulin or a substance possessing substantially the same activity as insulin, and (c) FGF or a substance possessing substantially the same activity as FGF.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

/ Rawlings
STEPHEN RAWLINGS

slr
October 1, 2003

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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